10/517584

PCT/CA 03/00976

05 SEPTEMBER 2003 05.09.03

REC'D 18 SEP 2003
WIPO PCT

PA 1044759

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

July 29, 2003

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: ***60/391,594***
FILING DATE: ***June 27, 2002***

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

L. Edelen

L. EDELEN
Certifying Officer

JC923 U.S. PTO 06/27/02

60395911 . 062702

A | Prov

Please type a plus sign (+) inside this box → +

PTO/SB/16 (8-00)
Approved for use through10/31/2002 OMB 0651-0032
U.S Patent and Trademark Office; U.S DEPARTMENT OF COMMERCE

JC973 U.S. PTO 60/391594

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Magdy	Younes	3611-55 Harbour Square, Toronto, Ontario, Canada M5J 2L1.

☐ *Additional inventors are being named on the ____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

PROCEDURE AND APPARATUS TO IMPROVE VENTILATOR TRIGGERING DURING ASSISTED VENTILATION

CORRESPONDENCE ADDRESS

Direct all correspondence to:

☒ Customer Number **24223** → Place Customer Number Bar Code Label here 24223 PATENT TRADEMARK OFFICE

Type Customer Number here

OR

☒ Firm *or* Individual Name	**Michael I. Stewart**
Address	**Sim & McBurney**
Address	**6th Floor, 330 University Avenue**
City	**Toronto** — State **Ontario** — ZIP **M5G 1R7**
Country	**Canada** — Telephone **(416) 595-1155** — Fax **(416) 595-1163**

ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 4

☒ Drawing(s) *Number of Sheets* 1

☒ Application Data Sheet. See 37 CFR 1.76

☐ CD(s), Number ____

☒ Other (specify) **Postcard**

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

☒ Applicant claims small entity status. See 37 CFR 1.27.

☒ A check or money order is enclosed to cover the filing fees

☐ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number ____

☐ Payment by credit card. Form PTO-2038 is attached.

FILING FEE AMOUNT ($): **$80.00**

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No

☐ Yes, the name of the U S Government agency and the Government contract number are ____

Respectfully submitted,

SIGNATURE [signature]

Date **2002-06-26**

TYPED or PRINTED NAME **Michael I. Stewart**

REGISTRATION NO. *(if appropriate)* **24,973**

Docket Number: **11788-2 MIS**

TELEPHONE **(416) 595-1155**

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

P19SMALL/REV05

INITIAL INFORMATION DATA SHEET

Inventor Information:

Inventor One Given Name:	Magdy
Family Name:	Younes
Postal Address Line One:	3611-55 Harbour Square
City:	Toronto
State or Province:	Ontario
Postal or Zip Code:	M5J 2L1
Citizenship Country:	Canada

Correspondence Information

Correspondence Customer Number: 24,223

Application Information

Title Line One:	PROCEDURE AND APPARATUS TO IMPROVE
Title Line Two:	VENTILATOR TRIGGERING DURING ASSISTED
Title Line Two:	VENTILATION
Total Drawing Sheets:	One (1)
Formal Drawings?:	Yes
Application Type:	Utility Patent
Docket Number:	11788-2 MIS:jb

Representative Information

Registration Number: 24,973

Continuity Information

This application is a:
Application One:
Filing Date:

TITLE OF INVENTION

PROCEDURE AND APPARATUS TO IMPROVE VENTILATOR TRIGGERING DURING ASSISTED VENTILATION

FIELD OF INVENTION

[0001] The present invention relates to assisted mechanical ventilation.

BACKGROUND TO THE INVENTION

[0002] With assisted ventilation (e.g. assist volume cycled ventilation, pressure support ventilation and proportional assist ventilation) ventilator cycles are triggered by the patient and are intended to coincide with patient inspiratory effort.

[0003] The attached Figure of drawings shows tracings of flow, airway pressure (P_{aw}), and diaphragmatic pressure (P_{di}). The last signal represents patient inspiratory effort. Since patient effort is not normally monitored, triggering is based on indirect signs. In current ventilators, triggering occurs when flow becomes inspiratory and exceeds a set level (see arrow in the flow channel). This is referred to as flow triggering. Alternatively, with pressure triggering, the cycle is triggered when P_{aw} decreases below PEEP (positive end-expiratory pressure) by a set amount (arrow in P_{aw} channel).

[0004] It can be seen from the Figure that, in the illustrated case, patient effort began well before actual triggering occurred (vertical lines). This delay in triggering is extremely common and results in ventilator cycles being out of phase with patient effort, causing discomfort and excessive work of breathing. The delay is related to the fact that expiratory resistance is usually high in ventilated patients and expiratory time is frequently too short to allow lung volume to return to FRC (functional residual capacity) before the next effort begins. At the onset of inspiratory effort, therefore, elastic recoil pressure is not zero (DH, dynamic hyperinflation). Inspiratory effort must first increase enough to offset the elastic recoil pressure associated with DH before flow can become inspiratory, and/or before P_{aw} decreases below PEEP, in order to trigger the ventilator.

[0005] I propose a new approach that would permit the ventilator to detect inspiratory effort much sooner than is possible with current techniques (flow or

pressure triggering). According to the equation of motion during mechanical ventilation:

$$P_{mus} = Volume*E + Flow*R - P_{aw}$$

[0006] Where P_{mus} is patient's muscular effort and E and R are the elastance and resistance of the respiratory system, respectively.

[0007] Prior to the onset of inspiratory effort in late expiration, there is no inspiratory P_{mus} and expiratory flow is largely generated by the stored elastic energy, given by [volume*E] with occasional contribution from expiratory muscles. As volume decreases during expiration, the elastic pressure driving flow also decreases. A certain pattern (trajectory) of decelerating expiratory flow develops in the absence of inspiratory effort. Once effort starts, a new inspiratory force of increasing magnitude is introduced. This results in expiratory flow now decreasing at a faster rate than established earlier. This is seen in the Figure as a clear "knee" in the flow tracing at the points where inspiratory effort (P_{di}) begins (vertical lines). Because P_{aw} during expiration is determined by expiratory flow and the resistance of the exhalation tubing and valve, a change in trajectory of expiratory flow results in a corresponding change in trajectory of P_{aw} with a magnitude that depends on exhalation resistance.

SUMMARY OF INVENTION

[0008] The present invention utilizes the point of change in trajectory in flow and P_{aw} to identify the onset of inspiratory effort in real time. The resulting signal demarcating onset of inspiratory effort is then used to trigger a new ventilator cycle.

[0009] While such identification of onset of effort can be done from the flow signal alone, it is advantageous to incorporate trajectory changes in P_{aw} as well. Thus, when exhalation circuit resistance is high, the change in flow, for a given rate of P_{mus} at the beginning of effort, will be attenuated while the change in P_{aw} trajectory will be enhanced. Utilizing both signals, therefore, provides a more robust signal under different conditions. Furthermore, when the change in flow trajectory is due to inspiratory effort, the change in pressure must be in an inspiratory direction. There are other artifactual reasons for a change in flow trajectory but these are usually not associated with a change in pressure in the correct direction. These reasons include transient changes in exhalation resistance or the exhalation valve, water in the tubing...etc. Insisting on a change in both signals in the right direction (both flow and

pressure moving in an inspiratory direction) helps distinguish noise from true onset of inspiratory effort, thereby minimizing false triggering.

[0010] Although a number of mathematical methods can be used to identify a change in trajectory, a simple and effective approach is to obtain the time derivative of the signal (flow and/or Paw) with suitable filtering. A change in trajectory appears as a step change in the time derivative. Inspiratory onset can then be identified when the derivative value increases by a specified amount (trigger sensitivity) and the increase is sustained for a specified time (e.g. 50 msec).

[0011] There are several approaches to incorporate the information contained in the pressure signal in order to enhance the information obtained from flow. One such approach is to make identification of inspiratory onset from flow conditional on the presence of similar changes in P_{aw}. This approach may result in many missed onsets if exhalation resistance is very low, or in the presence of active exhalation valve that controls P_{aw} during exhalation at a specified value regardless of flow. A more comprehensive and robust approach that applies under all ventilator conditions is to generate a P_{mus} signal using the equation of motion (above). This signal effectively combines the changes in P_{aw} and flow and is independent of exhalation tube resistance or the manner in which the exhalation or PEEP valves operate.

[0012] To generate a P_{mus} signal, it is necessary to insert values of E and R (see equation above). If these are known, the actual values can be inserted. If not, default values can be used (e.g. average E and R values in ventilated patients). The accuracy of these values is not critical for this application. Errors in assumed E and R values will result P_{mus} slope values that are different from zero, even when inspiratory muscles are silent, as during expiration. However, there will still be a trajectory change in the calculated P_{mus} signal at the time of inspiratory onset, and this can be detected mathematically as described for flow above.

BRIEF DESCRIPTION OF DRAWINGS

[0013] The Figure of drawings contains tracings of flow, airway pressure (P_{aw}) and diaphragmatic pressure (P_{di}) for a patient.

GENERAL DESCRIPTION OF INVENTION

[0014] The apparatus for implementing the triggering procedure of the invention can be incorporated within the ventilator or can be freestanding with its

output (trigger signal) gated to the ventilator using appropriate connections. In either case, the apparatus consists of:

[0015] (1) Means to monitor expiratory flow and airway pressure by use of an appropriate flow meter, transducers and signal conditioning components.

[0016] (2) Computer that carries out the following functions:

(a) Sampling and storing flow and pressure data during exhalation,

(b) Integrating flow to obtain volume, and

(c) Applying mathematical functions in real time to the data. In the preferred embodiment, the equation of motion is applied to fresh pressure, flow and volume data, using inputted or default values for E and R. The resulting P_{mus} data are then subjected to differentiation to obtain the time derivative. New values for the time derivative are compared with those obtained earlier. When a change is detected that exceeds a set value (e.g. 5 cmH_2O/sec), sustained over a specified period (e.g. 50 msec), onset of inspiratory effort is identified and a triggering output signal is generated.

[0017] (3) Means to communicate the trigger output signal to the triggering mechanism of the ventilator.

SUMMARY OF DISCLOSURE

[0018] In summary of this disclosure, the present invention provides an improved triggering of ventilation cycle in assisted ventilation. Modifications are possible within the scope of the invention.